Commentary

The Perils of Providing Medical Opinion
A State Medical Association's Experience

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After nearly 20 years, the California Medical Association (CMA) is reconsidering its responsibility to provide opinions on questions of clinical medical practice. Lawsuits prompted this reconsideration. We describe the CMA's experience with a medical practice opinion program and the benefits and risks to a professional association of participating in the assessment of technology.

Background

The California Medical Association has an active tradition of involvement in scientific and educational affairs. Its 1856 charter gives the association's purpose: "To promote the science and art of medicine; the care and well-being of patients; the protection of the public health and the betterment of the medical profession." The creation of the CMA's Scientific Board in 1963 gave these activities added emphasis.

The board is a forum of chairs of the association's 24 scientific advisory panels, groups formed as a specialty-based resource to plan educational activities, prepare the Epitomes section of THE WESTERN JOURNAL OF MEDICINE, and provide scientific opinion to CMA, its component societies, and the public.

The advisory panels reflect both a geographic mix and a balance between academic physicians and those in private practice. Each advisory panel has about 16 members, including a chair or senior representative of the appropriate specialty department of the eight California medical schools; the principal officers of the major statewide specialty societies; and several other members with distinguished scientific or educational credentials elected to represent privately practicing physicians in the specialty.

In the early 1970s, the California Medical Association began receiving an increasing number of requests for opinions on medical practice issues. The questions came from newly formed medical care foundations, health insurance carriers, the State Department of Health Services' Medicaid program, the Medical Board of California (then known as the Board of Medical Quality Assurance), hospital medical staffs, and from various individuals. Most of the inquirers wanted to know whether a particular medical procedure, technique, or device was accepted medical practice. Underlying many of the questions was a payer's need to make a reimbursement decision. But concerns about hospital medical staff privileges, county medical society membership, and medical board investigations triggered questions as well. All of these groups were seeking an authoritative source for opinions that were likely to have far-reaching effects.

As a result of these requests for medical opinions and the commitment of the CMA to promote the science and art of medicine, the medical practice opinion program was initiated in 1974.

The Medical Practice Opinion Program

The CMA Medical Practice Opinion Program selectively accepted requests to review emerging, new, and, to a lesser extent, established medical and surgical practices, procedures, and medical care devices for their safety, effectiveness, limitations, and general level of acceptance in the medical community.

The program never considered cost and benefit questions or insurance coverage issues. The opinions given were based on the personal knowledge and experience of the specialists who served on the scientific advisory panels and consultants selected by the panel members. The opinions addressed broad issues—not medical care given in a specific case.

Persons or organizations seeking CMA review of a medical practice question submitted a written request explaining the reason for the question and providing sufficient background to describe the issue. The request then was sent to the chairs of the 24 scientific advisory panels to determine whether to accept the question and, if so, which specialties should contribute to an answer.

Once accepted, the question was circulated to members of the appropriate advisory panels with relevant articles from peer-reviewed journals, review reports from authoritative organizations such as the National Institutes of Health, policy statements from national specialty societies, and other information from recognized experts in the field. All of the panel comments received were distilled into a summary opinion that was reviewed by the panel chair(s); returned to the individual respondents for ratification; and presented to the CMA Commission on Quality Care Review, a multispecialty oversight body, for final approval.

Unanimity was sought on all medical practice opinions, but when agreement could not be reached, an opinion was drafted to reflect the broadest common ground among the respondents, with the points of difference stated clearly, without bias or attribution to specific specialties or persons. The individual comments of the advisory panel members remained confidential throughout this process. There was a review mechanism to assure that all opinions in circula-

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tion remained current or were dropped. The final opinion was shared with the original inquirer and published in this journal.

During the first 15 years of its existence, the Medical Practice Opinion Program grew in volume and sophistication. The opinion formulation process became more formal. Guidelines for administering the program were developed and approved by the governing council of the CMA in 1975 and were periodically reviewed and revised. While the CMA never solicited inquiries to the program, the number of questions steadily increased. During the years 1972 to 1987, nearly 350 opinions were issued.

Legal Problems Surface

The first lawsuit generated by a medical practice opinion was filed in 1982 and involved a physician's challenge to an opinion concerning the surgical procedure, bilateral carotid body resection. The opinion was a consensus of 46 panel members from chest diseases, internal medicine, and general surgery and stated that the procedure was not accepted medical practice. The physician plaintiff maintained that the procedure was accepted practice and that he had suffered substantial economic loss as a result of the opinion and was entitled to compensation under federal antitrust laws.

Most insurance carriers denied coverage for bilateral carotid body resection (Blue Shield was later added as a defendant in the lawsuit), and in 1980 the Joint Commission on Accreditation of Hospitals warned the hospital where the plaintiff practiced that allowing unacceptable surgical procedures such as bilateral carotid body resection could jeopardize the hospital's accreditation. These events, it was alleged, flowed from the issuance of the medical practice opinion.

Judicial proceedings extended over six years and ultimately resulted in a judgment in favor of the CMA. In dismissing the case, the judge noted that "the conduct . . . is entirely consistent with organizations and professions acting in good faith to fulfill their legal and professional responsibilities." The Association's defense costs in this suit, covered by the CMA's liability insurance carrier, were estimated to be $250,000.

A second lawsuit, filed in 1988, also was a complaint for damages under federal antitrust laws. The plaintiff was a laboratory that did cytotoxic testing for food allergy and advised its clients on the basis of test results to avoid certain foods and substances and to substitute others. The trigger for the suit was a CMA medical practice opinion stating that cytotoxic testing was not accepted medical practice. The plaintiff claimed that this opinion was part of a conspiracy by the allergy and medical associations to suppress a nontraditional method of allergy testing so that the incomes of "traditional" allergists would be protected from competition.

In an action preceding the lawsuit, the Laboratory Field Services Section of the State Department of Health Services decided to regulate laboratories engaged in cytotoxic testing as other clinical laboratories were regulated. Regulation by the State Department of Health Services entailed mandatory proficiency testing, which the cytotoxic testing laboratories resisted. Laboratories offering cytotoxic testing maintained that they were not engaged in the practice of medicine but offered only nutritional counseling. To bring these laboratories under state regulation, it was necessary to establish that they were purporting to diagnose or treat disease.

The Medical Board of California opined that the cytotoxic test was being used to diagnose food allergy. That determination allowed the State Department of Health Services to impose proficiency testing requirements on cytotoxic laboratories. The combination of declining insurance reimbursement for cytotoxic testing and the imposition of proficiency testing regulations created the economic hardship that the plaintiffs in this second lawsuit attributed to the medical practice opinion issued by the CMA.

This action also was resolved in the CMA's favor in 1990 at a relatively early stage of the proceeding but cost the CMA $50,000—the amount of the deductible copayment in the association's liability insurance policy. Additional legal expenses incurred by all plaintiffs meant that well over a quarter of a million dollars was spent to have this case dismissed.

Program Changes in Response to Legal Concerns

After the second lawsuit was filed in 1988, legal counsel recommended that the CMA impose an immediate moratorium on medical practice opinions until the risks of the program could be assessed. The only medical practice questions accepted after 1988 were those generated by governmental entities such as insurance companies serving as claims intermediaries for the Medicare program in California. Responses to agents of government were considered protected by the Noerr-Pennington doctrine, which is based on the constitutional rights to freedom of speech and to petition the government. Other inquiries were referred to other sources for scientific information.

Pros and Cons of Medical Practice Opinion Programs

Medical practice guidelines are intended to protect patients from unproven, unsafe, and inappropriate procedures. Insurance firms rely on such guidelines to make rational reimbursement decisions. By generating medical practice opinions, physician organizations help assure that reimbursement patterns reflect community standards and that resources are neither wasted on outmoded technologies nor inappropriately denied for needed care. Such opinions become increasingly valuable as governmental battles are waged for scarce health care dollars and medical groups and others seek to expand health insurance coverage to uninsured populations. Moreover, organized medicine's willingness to accept some liability risk in pursuit of patient protection contributes to the image of the medical profession as socially responsible and dedicated to the public good.

The legal defense costs of challenged opinions are potentially devastating, however. The costs associated with defending an antitrust lawsuit can easily consume a substantial part of a medical association's financial resources, even if the suit has no basis. Because of the potential for lengthy court proceedings and punitive awards of treble damages, association liability insurance providing coverage for antitrust actions can be prohibitively expensive—if available at all.

Just as physicians may practice defensive medicine to avoid lawsuits, medical associations are pressured to buttress activities such as the Medical Practice Opinion Program with attorney-recommended safeguards to reduce legal liability exposure. The consequence may be a program increasingly ponderous, cautious, and unresponsive to the needs of its constituency.

Risk reduction strategies implemented by other associations range from elaborate disclosure of interest statements

by each respondent to the suppression of negative opinions and the issuance of positive opinions only.

Interestingly, the physicians providing opinions to the CMA were among the strongest supporters of the program—despite their risk of becoming embroiled in legal wrangles over contested opinions. No physician expressed reluctance to participate, and those who were deposed on the two lawsuits discussed earlier were willing witnesses to the value of the Medical Practice Opinion Program. All 24 of the Scientific Board's advisory panels have voted repeatedly to support the program and to petition the CMA Board of Trustees for an end to the moratorium on the issuance of scientific opinions. Some physicians expressed resentment that this type of program may become another casualty of needless intrusion and interference by the American legal system. The Advisory Panel on Neurosurgery recommended in 1990: "If the medical practice opinion program is discontinued or modified, the CMA should use all means available to inform its membership and the general public why it cannot respond to questions on medical practice."

The CMA adopted a cautious approach. In 1989 its Board of Trustees voted to continue the moratorium indefinitely while exploring options such as liability exemption legislation and other means to reduce liability risk to a level deemed acceptable before reactivating the program.

Possible Solutions

The goal of the CMA is to continue the Medical Practice Opinion Program if the risk of legal liability can be reduced to an acceptable level. These are the solutions that are now being assessed:

- Eliminate the Medical Practice Opinion Program.

This option has the appeal of saving the medical association from the future risk of lawsuits arising from program opinions. On the negative side, it is clear that determinations of acceptable medical practice will be made—if not by organized medicine, then by others. If physicians abrogate their role as arbiters of quality-care decisions, these decisions are likely to be made by people for whom good patient care and honest science are not the highest priority.

- Continue the Medical Practice Opinion Program but respond only to requests from governmental entities.

While this option provides the CMA with a limited sense of security based on the applicability of the Noerr-Pennington doctrine, it severely limits the number of questions that can be accepted. Our data suggest that at the very least, more than 80% of questions would be eliminated—probably more as the program's visibility diminished.

- Direct all requests for medical opinion through the Medical Board of California.

This option would require an agreement, adopted through the agency regulatory process, that the state medical board receive all questions, refer them to the CMA or other medical associations for comment, and serve as the repository of final opinions. The Medical Board of California seems willing to consider this approach, based on its perception of the value of a state-based medical assessment program. To obtain the benefits of legal immunity that medical board oversight would provide, however, the board must, by law, engage in active supervision of the program on whose opinions it relies. This degree of supervision over a CMA program by a state agency could be unacceptable to the CMA. It could require more resources than the board wishes to devote to the enterprise. The potential for political influence in such an arrangement also is a concern.

- Seek immunity for this and similar opinion programs through legislative action.

This approach would require enacting legislation containing a statement that clearly expresses the California legislature's intention to replace competition with regulation for the purpose of ensuring the provision of effective and efficient health care to Californians; and the creation of an actively supervised program to assist in the dissemination of medical information necessary to the state's health, safety, and welfare. The new entity would be a Committee on Health Care Technology that would provide a framework for the advance notice of opinions under consideration, referral of issues to groups such as the CMA that meet an established standard, and procedures for due process and the appeal of adverse decisions. If enacted, such a law could allow the CMA and other professional associations to provide scientific opinion freely, without fear of unreasonable legal risk. The disadvantages of this option include the difficulty in enacting such legislation over predictable objections from trial attorney groups and the potential political influences that state control of the program could bring.

- Reactivate the Medical Practice Opinion Program and resume full activity.

Adopting this action would require the recognition that the costs of the program, including legal defense costs, are reasonable given the value of the program to the profession and to patients.

Conclusion

Failure to reactivate the Medical Practice Opinion Program allows a program designed for the protection of patients and the greater public good to be destroyed by intimidation. Medical associations must endeavor to prevent persons from using the legal system to protect practice methods that have been judged unacceptable. Although we cannot envision a risk-free world, medical associations must accept their responsibility to discourage such suits by a strong defense.

Society needs the assistance of all qualified professional associations to evaluate the effectiveness of medical care. The medical profession needs reasonable professional autonomy in expressing scientific opinion. Most important, patients need programs such as the Medical Practice Opinion Program.